

JAN - 4 2001

K002863

510(k) Summary

Submitted by: Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
2000 M Street NW (#700)
Washington, DC 20036
202-261-1000

December 28, 2000

On behalf of Tokuyama America, Inc.
510(k) Submission: Tokuyama Palfique Estelite LV

The product is a low viscous, light cured hybrid composite tooth shade resin material. It is intended for use in various dental procedures, including restoration of cavities, cervical caries, deciduous teeth, incipient caries, and the repair of temporary resin crowns. It is marketed in two viscosity levels; High Flow and Low Flow.

The product incorporates the manufacturer's Sub-Micron Spherical SiO_2 - ZrO_2 (0.4 μm) and Sub-Micron Spherical SiO_2 - TiO_2 (0.1 μm) both of which are also used in the manufacturer's Palfique Estelite Paste (K980051), Palfiquelite Posterior (K913099) and Palfique (K897010). The product incorporates well known monomers for filling material, including those used in the manufacturer's Palfique Estelite Paste (K980051). Palfique Estelite LV is substantially equivalent to Palfique Estelite Paste (Tokuyama - K980051), NTL-Flow (Bisco, Inc. - K974483), Flow Line (Heraus Kulzer, Inc. - K990756), and Tetric Flow (Ivoclar North America, Inc. - K993783).

Because Palfique Estelite LV is available in two viscosity levels, dentists have more flexibility in addressing varied clinical situations, as contrasted to other low viscosity resins which are available in only one viscosity level. The combination of Sub-Micron Spherical SiO_2 - ZrO_2 and SiO_2 - TiO_2 fillers permits higher filler content levels. Higher surface glossiness allows for superior aesthetics while the low degree of color change during curing facilitates selection of the proper shade by the dentist. A comparison of these properties with equivalent products is presented in the following table.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tokuyama America, Incorporated
C/O Daniel J. Manelli
Farkas & Manelli, P.L.L.C
2000 M Street Northwest, Suite 700
Washington, District of Columbia 20036

Re: K002863
Trade Name: Tokuyama Palfique Estelite LV
Regulatory Class: II
Product Code: EBF
Dated: December 28, 2000
Received: December 28, 2000

Dear Mr. Manelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

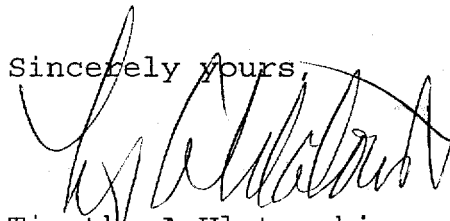
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Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002863

Device Name: Tokuyama Palfique Estelite LV

Indications For Use:

For use as a tooth shade resin material in dental procedures.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use



(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

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